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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,151	10/14/2003	Garry P. Nolan	STAN-426CON	5878

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EXAMINER	
HAQ, SHAFIQUL	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,151	NOLAN ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-5, drawn to a peptide, classified in class 530, subclass 300.

   II. Claims 6-13, drawn to a complex of a fluorophore with a peptide, classified in class 530, subclass 328.

   III. Claims 14-17, drawn to a method of binding a peptide to a fluorophore, classified in class 436, subclass 546.

   IV. Claims 18-23, drawn to a method detecting a fluorette, classified in class 436, subclass 172.

   IV. Claims 24-28, drawn to peptides of defined sequences, classified in class 530, subclass 327.

   The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

2. Inventions of group I and group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, group I requires a peptide of about 8 amino acid sequence fused to a presentation sequence of SEQ ID No 112 (see claims 1-5), which is not required by the invention of group II. Invention of group II is a complex of a fluorophore dye with a peptide of defined sequences represented by different

SED IDs (e.g. SEQ ID NO:1, SEQ ID NO:2), which is not required by the invention of group I.

3. Inventions of 1) group III and 2) each of groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, group III is a method of binding a peptide to a fluorophore dye but the method does not require fused peptide-presentation structure (i.e. fused peptide and SEQ ID N:112) of group I or any of the defined peptide sequences of group II represented by different SEQ IDs (of claim7) bound to a fluorophore. Moreover, Group I and II requires Texas Red, Rhodamine Red, Oregon Green 514 and Fluorescein, which is not required by the method of group III.
4. Inventions of 1) group IV and 2) each of groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, group IV is a method of detecting a fluorette but the method does any of the defined peptide sequences of group II represented by different SEQ IDs (of claim7) bound to a fluorophore in the detection method. Moreover, Group I and II requires Texas Red, Rhodamine Red, Oregon Green 514 or Fluorescein bound to a peptide sequence, which is not required by the method of group III.

5. Inventions of group III and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, group III is a method of binding a peptide to a fluorophore and group IV is a method of detecting f fluorette and the method of group IV requires a fluorette fused to a target analyte, which is not a required component in group III.
6. Inventions of 1) group V and 2) each of groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group V encompasses a large number of peptides of defined sequences of about 12-13 amino acids and the peptides are not required by any of the groups I-IV. The peptides required by groups I-IV (i.e. peptides of about 8 amino acids, SEQ ID NO: 1, 2) are different from the peptides of group V.
7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper. In addition, the search for each of the distinct inventions of Groups I-V is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for

patentability is different in each case. A patentability determination for Invention I would require an assessment of the novelty and unobviousness of the peptide of 8 amino acids that binds to a peptide, while a patentability determination for inventions of groups II would require an assessment of the novelty and unobviousness of the complex of a fluorophore with a peptide represented by defined SEQ IDs. Similarly, a patentability determination for inventions of groups III would require an assessment of the novelty and unobviousness of the method of binding a peptide of 8 amino acid to a fluorophore, while a patentability determination for inventions of groups IV would require an assessment of the novelty and unobviousness detection method of fluorette requiring fused target analyte and a presentation structure. Finally, patentability determination for inventions of groups V would require an assessment of the novelty and unobviousness of a large number of different peptide sequences as shown in claims 25-28. Therefore, it will be an undue burden to examine all the inventive Groups in one application.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

9. This application contains claims directed to the patentably distinct compounds.

   a) Peptide sequences represented by each of the SEQ ID in claims 6-11, comprise a separate invention under 35 USC 121 as being distinct compound for having different amino acids and for having different arrangements of amino acids in the sequences.

Therefore, **in the event that an election of Group II is made**, a single SEQ ID sequence must be elected.

b) Each of the formula of peptide sequences in claims 24-27, comprise a separate invention under 35 USC 121 as being distinct compound for having different amino acids and for having different arrangements of amino acids in the sequences.

Therefore, **in the event that an election of Group V is made,** one compound must be elected from the following group of peptide sequence formula set forth below:

(A). X_1-X_2-X_3-X_4-Y-W-T-X_5-M-F-Y-X_6
(B). X_1-P-H-X_2-P-M-Y-W-T-X_3-V-F
(C). X_1-X_2-W-X_3-Y-X_4-W-D-W-T-X_5-F-W
(D). Y-X_1-X_2-X_3-X_4-X_5-W-W-X_6-Y-Y-X_7

(A)-(D) are unrelated because they are structurally distinct by having different amino acids and different arrangement of amino acids in the sequence.

Furthermore, each of formula (A)-(D) compound comprises a large number of patentably distinct species by their selection of various amino acids for each variable in the formula.

Therefore, **where an election of formula (A)-(D) is made,** an election of a single species compound is further required by electing a single amino acid for each variable in the sequence.

c) This application also contains claim directed to the following patentably distinct fluorophore compounds:

(E). Texas Red
(F). Rhodamine Red
(G). Oregon Green 514
(H). Fluorescein

E, F, G and H each comprise a separate invention under 35 USC 121 for having different chemical structures. Texas Red, Rhodamine Red, Oregon Green 514 and Fluorescein are structurally divergent and have different chemical properties and thus constitute patentably distinct compounds.

Therefore, **In the event that an election of any one of Groups I or II is made,** one fluorophore compound must be elected from the above groups (E)-(H).

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 & 13 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(1)

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 8:00AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHAFIQUL HAQ
EXAMINER
ART UNIT 1641

LONG V. LE
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